Remarks

Claims 1 to 25, 28 to 33, 35 to 37 and new claims 38 to 40 are pending in this application of which only claims 1 and 24 are in independent form. Support for new claims 38 and 39 can be found in the claims they depend on. Support for new claim 40 can be found, e.g., in the paragraph bridging pages 14 and 15.

35 USC §112 rejection

On page 3, the Office rejected claims 11 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Office suggested this is due to the phrasing "such as" within the said claims.

In response, applicants have amended the claims and introduced new claims 38 and 39.

35 USC §102 (b) rejection

Also on page 3, the Office rejected claims 1-10, 12-17, 23-25, 28-31, 36 and 37 under 35 USC §102(b) as being anticipated by US Patent 5,569,458 to Greenberg ("Greenberg").

The Office referred to col. 2, line 64, col. 3, lines 1 to 30 and 33 to 46 for support of this rejection.

Greenberg discloses a vitamin and mineral formulation combined with digestive enzymes and including the herb goldenseal to prevent the enzymes from "eating up" the other nutrients. Greenberg recognizes that the proportioning of the ingredients is

important for absorption by the body.

Greenberg also discloses a composition of a wide variety of vitamins, minerals and herbs in the table bridging col. 2 and 3. Different milligram (mg) and mcg amounts of these ingredients are provided. In the paragraph starting on line 29 of col. 3, Greenberg also discloses a 138mg synergistically balanced base of a mixture of proteins including, e.g., bromelain and papain as well as proanthocyanidins and lemon bioflavonoid complex.

Claim 1 has been amended to require that:

> said one or more plant protease and/or animal protease have a total concentration of 20% to 60% by weight of active constituents in the composition . . .
>
> said flavonoids and/or flavonoid-containing substances have a total concentration of 10% to 50% by weight of active constituents in the composition" (emphasis added).

Support for these amendments can be found, e.g., in the paragraph bridging pages 9 and 10 and in the paragraph bridging pages 12 and 13.

Applicant submits that Greenberg does disclose these limitations as required for an anticipating reference.

Claim 24 is now in independent form and is directed to a food product for food supplementation. Greenberg is directed to a formulation contained in capsules (see Summary of the Invention and claim). The Office is directed to the paragraph bridging pages 19 and 20 of the present disclosure, where the claimed food products are set forth as a category separate from the compositions described before. Accordingly, applicant respectfully submits that Greenberg does not disclose this limitation of claim 24 as required for an anticipating reference.

35 USC §103 (a) rejection

On page 4, the Examiner rejected claim 1-10, 13-19, 20-22, and 35 under 35 USC §103(a) as being unpatentable over Greenberg, in view of Vetvicka et al. (JANA, 2002, Vol. 5, No. 2, p. 5-9) and Ochao et al. (Journal of Parenteral & Enteral Nutrition, 2001, Vol. 25, No. 1, p. 23-29) and further in view of Birt et al. (Pharamacology & Therapeutics, 201, Vol. 90, p. 157-177).

The Office acknowledged that Greenberg does not teach ß-glucan (polysaccharide), L-arginine (amino acid), taxifolin and luteolin (flavonoids) and lycopene (carotinoid).

However, the Office stated that Vetvicka et al. teach ß-glucan, Ochao et al. teach L-arginine and Birt et al. teaches taxifolin and luteolin and lycopene.

The Office expressed the opinion that it would have been obvious to the person skilled in the art to replace the polysaccharide taught by Greenberg (mucopolysaccharide) with the ß-glucan taught by Vetvicka et al., the amino acids taught by Greenberg with the L-arginine disclosed in Ochao et al. and the flavoids and carotenoids taught by Greenberg with taxifolin and luteolin and lycopene as taught by Birt et al. in view of certain advantageous properties taught for each of these components in the respective reference.

As already Greenberg points out, the user of multivitamins can experience a host of disadvantageous effects. As applicant noted in his last response, studies show that therapy with certain enzyme combinations have negative effects on the further development of an ailment. As an example, applicant provided the Office with a summary of a study conducted by Dörr et al. Here, a combination of papain, trypsin &

chymotrypsin, was tested for the treatment of oral mucositis after radiotherapy. While the combination was well tolerated by the patients, the study revealed, after over 1 to 6 weeks, a significant difference **in favor of the placeobo group**. Leipner, a previously applied reference, also reported negative effects of certain proteinases (p. 781, first full paragraph). Notably, Birt et al.'s finding on page 168 (on which the Office relies for disclosure of the flavones taxifolin and luteolin) appear to be based on experiments done in isolation, i.e., without evaluation of these substances when combined with any other substance, in particular the hydolases of the present invention. The authors also point out that more *in vivo* studies are needed (page 169).

Thus, the fact that a certain "supplement" might provide advantageous results when administered alone or when combined with a first set of ingredients, does not imply that it does so with a second set of ingredients.

In addition and as set forth in the context of the anticipation rejection, applicant has further defined the ranges in which the plant protease(s) and/or animal protease(s) and flavonoid(s) and/or flavonoid-containing substance(s) are present which are not taught or suggested by the cited art.

Applicant further submits that the Office does not appear to have provided any reason why the specific compositions as claimed, e.g., in claims 19 to 22, would be obvious in view of the prior art (see also Examples 1 to 4 on which these claims are based). Accordingly, applicant respectfully submits that no *prima facie* case of obviousness has been established. E.g., the Office has not shown where sodium selenite as specifically mentioned in claims 19 and 20 is taught or suggested by the references cited in this rejection.

On page 5, the Office rejected claim 1-11, 32 and 33 under 35 USC §103(a) as being unpatentable over Greenberg, in view of Rayman et al. (The Lancet, 2000, Vol. 356, p. 233-241; "Rayman").

The Office acknowledged that Greenberg does not teach sodium selenite as selenium-containing substance in a concentration of 0.01 to 0.1%.

The Office did, however, express the opinion that Rayman teaches a dose of 200µg per day and discloses certain advantageous features of this addition. As set forth in the context of the anticipation rejection, applicant has further defined the ranges in which the plant protease(s) and/or animal protease(s) and flavonoid(s) and/or flavonoid-containing substance(s) are present.

Applicant submits that (1) there is no indication that the daily intake of 200µg as described by Rayman correlates to the concentration specified, in particular in context of the concentrations of the other ingredients as now set forth in claim 1. Also, the studies presented by Rayman do not render obvious or even take into account the effects of co-administration of sodium selenite with other components, in particular the components of the present invention. In fact, the attached abstract of the Kemidjian-Schumacher publication (that Rayman cites on page 234) states that participants were simply given selenite or placebo tablets. As set forth in the paragraph bridging pages 14 and 15, the hydrolases, especially the proteases bromelain and papain or bromelain and papain and trypsin and/or chemotrypsin improve through their immunomodulary effect the immunomodulatory properties of sodium selenite (see also new claim 40), which is significant, in particular in view of the enzyme combination studies discussed above.

Applicants submit that there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. (MPEP §2141, III (G)). However, assuming for argument's sake only, that there was a teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify Greenberg or to combine its teachings with Vetvicka et al., Ochao et al. and Birt et al., applicant respectfully submits that a combination of these references would have given the person of ordinary skill no reason to pursue the invention as presently claimed. Applicant submits that any beneficial results obtained with the claimed combination could not have been predicted for the person of ordinary skill in the art after reading the cited references (MPEP §2141, III (A) and (B)). Such a person could, for example, not have reasonably predicted that the stimulation of the immune system is particularly pronounced when the recited proteases are combined with sodium selenite as described in the paragraph bridging pages 14 and 15 of the specification. Also, neither Greenberg nor the remaining references cited provide a finite number of identified, predictable solutions, that would have provided the person of skill in the art with a reasonable expectation of success (MPEP §2141, III (C)).

In view of the above, applicant submits that *no prima facie* case of obviousness has been established for the inventions as presently claimed.

An early issuance of a notice of allowance is therefore respectfully requested.

The Commissioner is authorized to charge any fee deficiencies or overpayment to the undersign's deposit account 50-3135.

Respectfully submitted,

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